

REMARKS/ARGUMENTS

This is a "Replacement Amendment" and is a response to the Office Action mailed 03/17/2004. The Office Action mailed 03/17/2004 was a "Notice of Non-Compliant Amendment" with respect to Applicants' response to the Office Action mailed December 15, 2003. Applicants are providing the Replacement Amendment to correct the "Non-Compliant" issue by including the text of the withdrawn claims which was missing in the earlier version.

Claims 7, 13, 23-27, and 29-31 were withdrawn from consideration in this application. In response to a Requirement to Elect a Species in the Office Action mailed 07/18/2002, claims 7, 13, 23-26, and 29-31 were withdrawn from consideration. In the Office Action mailed 12/05/2002 claim 27 was indicated to be dependent upon non-elected claim 26 and therefore claim 27 was indicated to be non-elected.

The claims presented for examination in this application are: claims 2-6, 8-12, 14-22, 28, and 32-35.

The Office Action mailed December 15, 2003 has been carefully reviewed. Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested.

35 USC 103 Rejections

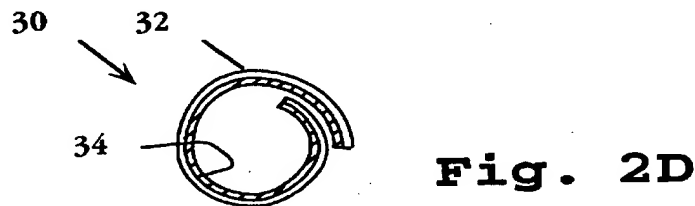
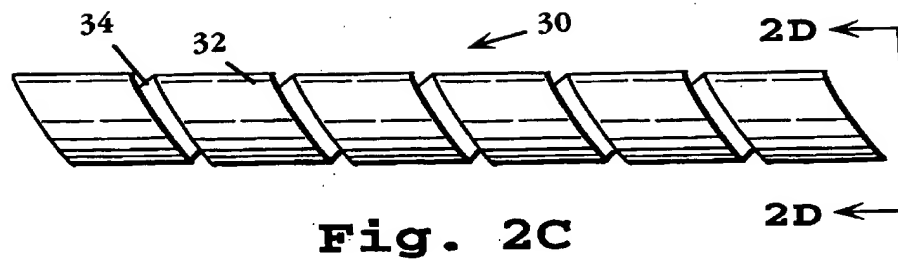
In numbered paragraph 5 of the Office Action mailed December 15, 2003, claims 2-6, 12, 14-22, 28, and 34-35 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Phan et al (U.S. Patent No. 5,647,242) in view of Maynard (U.S. Patent No. 5,405,337). Claims 8-11 were not mentioned in paragraph 5; however, Applicants believe that claims 8-11 are likely part of this rejection and will proceed as though claims 8-11 are also rejected under 35

U.S.C. 103(a) as allegedly being unpatentable over Phan et al in view of Maynard (U.S. Patent No. 5,405,337).

In numbered paragraph 6 of the Office Action mailed December 15, 2003, claims 32-33 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Phan et al and Maynard (U.S. Patent No. 5,405,337) in view of Lee et al (U.S. Patent No. 6,059,815).

The Primary Phan et al Reference (U.S. Patent No. 5,647,242)

The Phan et al reference shows a drug-delivery device. The Phan et al drug-delivery device does not perform the functions of Applicants' claimed invention and does not have the structure of Applicants' claimed invention. The Phan et al drug-delivery device is shown in the drawing below and is described as follows, "As shown in FIG. 2, polymer member 32 is disposed on the outer surface of the endoprosthesis device, with the structural member on the inside. This arrangement is preferred in a device where the structural member is composed of a non-shape memory material or where the structural member is self-expanding. The polymer member, being formed of a shape-memory polymer, is self-restraining in its contracted state and serves to restrain the structural member as well. When the polymer member is activated for expansion, the structural member coexpands by virtue of its self-expanding design or in response to a stimulus, such as radial force from inflation of a balloon catheter." (Col 4, lines 66 & 67 and Col. 5, lines 1-10)



It is Applicant's position that none of the three references used in the Office Action show certain significant elements of Applicant's amended claims, and that it would not be obvious to combine the three references.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) include "Ascertaining the differences between the prior art and the claims at issue." Set out below are some of the key elements of Applicant's amended claims that are not shown in the Primary Phan et al reference.

Claim 1 – "a first unit comprising a first structure for at least positioning said apparatus, said first structure including a quantity of shape memory alloy and a quantity of shape memory polymer, said shape memory alloy having a longitudinally extending coiled configuration with more than one wrap, and said shape memory polymer comprising a cylinder, wherein said portion is positioned in said first unit such that changes in transition of said shape memory alloy causes said first unit to change position; and

a second unit connected to said first unit, said second unit comprising a second structure for at least positioning said apparatus, said second structure including a second quantity of shape memory alloy and a second quantity of shape memory polymer, said second quantity of shape memory alloy having a longitudinally extending coiled configuration with more than one wrap, and said second quantity of shape memory polymer comprising a cylinder,

wherein said portion is positioned in said second unit such that changes in transition of said shape memory alloy causes said second unit to change position thereby moving said apparatus."

Claim 11 – "a structure for at least positioning and bending a portion of said apparatus, said structure having an axis, said structure including a quantity of shape memory alloy in said portion, and a quantity of shape memory polymer in said portion,

said quantity of shape memory polymer is a cylinder, and wherein said quantity of shape memory alloy is positioned in said structure generally parallel to said axis and spaced from said axis, wherein said shape memory alloy is positioned in said device such that changes in transition of said shape memory alloy causes said apparatus to bend."

Claim 34 – "a composite of shape memory alloy forming a portion of said articulated tip with said composite of shape memory alloy having an axis that is offset from said central axis of the articulated tip for a catheter

and shape memory polymer forming a portion of said articulated tip, wherein said shape memory polymer comprises a cylinder, and wherein said composite of shape memory alloy is positioned in said articulated tip such that changes in transition of said shape memory alloy causes said articulated tip to bend."

Claim 35 – "a member constructed of shape memory polymer, wherein said shape memory polymer comprises a cylinder and said cylinder has a cylinder central axis,

said member including a shape memory alloy with a shape memory alloy axis located in or adjacent to said member in a position wherein said shape memory axis is offset from said cylinder central axis that will cause said device to bend upon a change in configuration of said shape memory alloy, and

means for selectively heating said shape memory alloy to cause a change in configuration thereof, whereby the change in configuration results in reversible positioning of said object."

The Primary Phan et al reference does not show the structural elements described above. The secondary Maynard reference does not show the missing elements. Since neither the Primary Phan et al reference nor the secondary Maynard reference show the structural elements of Applicants' claims described

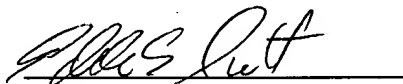
above, there can be no combination of the two references that would show the structural elements of Applicants' claims.

Further, there is no suggestion in the references to form a proper combination of the Phan et al and Maynard references to meet Applicants claimed invention. Also, the tertiary Lee et al reference does not show the missing elements and there is no suggestion in the references to form a proper combination of the Phan et al, Maynard, and Lee et al references to meet Applicants claimed invention.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated December 15, 2003 and the "Notice of Non-Compliant Amendment" in the Office Action mailed 03/17/2004 have been fully addressed and overcome. The present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



Eddie E. Scott
Assistant Laboratory Counsel
University of California
Lawrence Livermore National Laboratory
Attorney for Applicant
Registration No. 25,220
Tel. No. (925) 424-6897

Livermore, California

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